K133755

MAR 1 1 2014

Kowa Kowa Company. Ltd.

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510(k) Summary

Submitter information:

Applicant:	Kowa Company, Ltd. 4-14, Nihonbashi-honcho 3-Chome Chuo-ku, Tokyo, 103-8433 Japan Phone: +81-42-444-5079 Fax: +81-42-440-7618
Contact:	Hiroyuki Koide
Date summary prepared:	December 6, 2013

Device identification:

Device trade name:	KOWA SL-17
Classification name:	Biomicroscope, Slit-Lamp, Ac-Powered
Product code:	HJO

Identification of predicate device:
Kowa Company believes that this device is substantially equivalent to:
KOWA SL-15 manufactured by Kowa, 510(k) # K063640

Device description:
The KOWA SL-17 is a non-invasive ophthalmic device that is able to illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and a stand.

Intended use:
KOWA SL-17 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Technical characteristics:

Performance

To guarantee Performance, ISO10939 test was performed. The KOWA SL-17 met all requirements of the standard.

Electrical safety

To guarantee Electrical safety, IEC60601-1 test was performed. The KOWA SL-17 met all requirements of the standard.

Electromagnetic compatibility

To guarantee Electromagnetic compatibility, IEC60601-1-2 test was performed. The KOWA SL-17 met all requirements of the standard.

Optical safety

To guarantee Optical safety, ISO15004-2 evaluation was performed. The KOWA SL-17 met all requirements of Group 2 instrument in the standard.

Software evaluation

The Software of KOWA SL-17 was evaluated by FDA guidance, "Guidance for the content of premarket submissions for software contained in medical devices, 2005" and "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002". It was confirmed that the software was appropriate.

Biocompatibility

To guarantee biocompatibility, biocompatibility assessment was performed. The materials were used the same of the other legally marked devices in US. (#K063640)

Risk Management

The KOWA SL-17 was evaluated in accordance with ISO14971. The risk management of the device was deemed satisfactory. There was no remnant risk.

Substantial Equivalence

According to Guidance on the CDRH Premarket Notification Review Program 6/30/86, we determined the predicate device. From the above assessment, KOWA SL-17 and the predicate device is substantially equivalent.

Conclusion

The KOWA SL-17 is equipped with the fundamental technology features equivalent to the predicate device, and also delivers the equivalent level of safety. Therefore, it is concluded that there is no significant difference in the basic functions, safety and effectiveness between KOWA SL-17 and the predicate device.

Table 5-1: Comparison with Predicate Device

	Proposed device	Predicate device
Device Name	KOWA SL-17	KOWA SL-15
510(k) number	-	K063640
Indications for use or Scope	KOWA SL-17 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.	KOWA SL-15 is an ophthalmic device indicated for non-invasive illumination, magnification and observation of the human eye. It consists of a hand-held, battery powered slit-lamp biomicroscope with viewing and illumination optical systems and an AC-powered stand.
Slit lamp function and principal parts		
Illumination light source	White LED	Halogen lamp
Aperture diameter	Three selection (ϕ1, ϕ5, ϕ12mm)	ϕ12mm Fixed
Slit length	12mm	
Slit width	Three selection (0.1, 0.2, 0.8mm)	
Spot	ϕ1, ϕ5, ϕ12mm and shapes of ellipse	-
Light intensity	Adjustable continuously	Three selection (1/16, 1/4, Full)
Power supply	4pcs of AAA batteries (Alkaline or Ni-MH)	Lithium-ion rechargeable battery

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Kowa Company, Ltd.
% Mr. Hiroyuki Koide
4-14, Nihonbashi-honcho 3-chome
Chuo-ku, Tokyo, 103-8433
Japan

Re: K133755
Trade/Device Name: KOWA SL-17 slit lamp
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: January 14, 2014
Received: January 16, 2014

Dear Mr. Koide:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if know): K133755

Device Name: KOWA SL-17

Indications for Use:

KOWA SL-17 is intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. It is used to aid in the diagnosis of diseases or trauma which affect the structural properties of the anterior eye segment.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device

Andrew Yang -S
2014.02.24
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number K133755